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OTC Hydroquinone Meeting
July 10, 1996
10:00 A.M.
9201 Corporate Blvd., Conference Room S400

External Participant: Nonprescription Drug Manufacturers Association (NDMA)

Meeting Type: Feedback

Meeting Chair: Michael D. Kennedy

External Participant Lead: R. William Soller, Ph.D., Sr.V.P., Nonprescription Drug Manufacturing Association (NDMA)

Meeting Recorder: Michael D. Kennedy

FDA Attendees:

Syed Alam, DDDDP (HFD-540)
Arthur Baker, M.D., DODP (HFD-560)
Donald Dobbs, DODP (HFD-560)
William E. Gilbertson, Pharm.D., ODEV (HFD-10)
Abigail Jacobs, DDDDP (HFD-540)
Michael D. Kennedy, DODP (HFD-560)
Melvin Lessing, DODP (HFD-560)
Anne Mustafa, DODP (HFD-560)
Robert Sherman, DODP HFD-560)

External Constituents:

Representing the NDMA:
R. William Soller, Ph.D., Sr. V.P., Director Of Science and Technology, NDMA
Lorna Totman, Ph.D., Director of Scientific Affairs, NDMA
Thomas B. Fitzpatrick, M.D.,Ph.D., Professor, Department of Dermatology, Harvard Medical School
Pearl E. Grimes, M.D., Vice Chairperson, Department of Dermatology, UCLA School of Medicine
Howard I. Maibach, M.D., Vice Chairman, Department of Dermatology, UCSF School of Medicine
John L. O'Donoghue, V.M.D., Ph.D., DABT Director, Toxicological Sciences laboratory, Eastman Kodak Co.
J. Caroline English, Ph.D., DABT, Manager, Biochemical

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Toxicology Group, Eastman Kodak Co.
Gary M. Williams, M.D., DABT, Director of Medical Sciences, American Health Foundation

Other Attendees:

George Andrassy, Ph.D., DEP Corp.
Thomas Blake, Regulatory Consultant
Eugene Gans, Ph.D., Medicis Co.
Elizabeth Hinkle, Washington Drug Letter
A. H. Neis, E. T. Browne Co.
Jonah Shacknai, Medicis Co.
Ed Strauch, Kiwi Brands
Roger Williams, American Health Foundation

Meeting Objectives:

Discuss and address safety of the use of hydroquinone as an active ingredient in OTC skin bleaching drug products.

Discussion Points:

- Overview of the use of hydroquinone in the treatment of hyperpigmentation problems.
- Mechanism of action of hydroquinone in tumor formation in male Fisher rat.
- Two year gavage study of hydroquinone in rats.
- Genotoxicity test results
- Dermal application studies in F344 rats.
- Epidemiological mortality study of hydroquinone production/use cohort.
- Invitro percutaneous absorption of hydroquinone through human skin.
- Ochronosis-South African versus U.S. experience.
- Ochronosis-physicians recall survey.
- Voluntary industry label changes on hydroquinone products.
- Effectiveness and benefits of hydroquinone as an OTC product.

Decisions (agreements) reached:

A presentation on the safety of hydroquinone with respect to oral carcinogenicity study should be made to the Carcinogenicity Advisory Committee (CAC).

Unresolved issues:

FDA considers a 2 year dermal toxicity study of hydroquinone necessary to answer outstanding safety questions regarding hydroquinone.

Action Items:

Item	Responsible Person
Notify CAC Executive Secretary of need for meeting.	Mike Kennedy
Data presentation to CAC(Industry)	Dr. Soller (NDMA)
Data presentation to CAC(FDA)	Don Dobbs

Comments to Draft Minutes sent to attendees:

Abby Jacobs: I'm not sure that the need for a dermal study for hydroquinone is an unresolved issue. The CAC will only address the oral NTP study and its implications. The need for a dermal study was conveyed in 1992 and it is hard to conceive why it would not still be needed.

Syed Alam: I completely agree with Dr. Jacobs. Furthermore, the CAC will examine only the carcinogenicity data, and dose not determine the overall safety of the drug in question. Therefore, the "Decisions (agreements) reached" section should be modified to read: A presentation on the safety of hydroquinone "with respect to oral carcinogenicity study" should be made to the Carcinogenicity Advisory Committee (CAC).

Minutes preparer: _____

for Michael Kennedy